SECTION 4 - 510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

FEB - 8 2008

510(k) number:
K070126

Date Prepared:
January 10, 2007
Revised February 5, 2008

Applicant Information:
SentreHeart
2468 Embarcadero Way
Palo Alto, CA 94303

Contact Person:
Linda Guthrie, Manager Regulatory Affairs
Phone Number: (650) 354-1200
Fax Number: (650) 354-1204

Device Information:

Trade Name:	Occlusion Balloon Catheter
Classification:	Class II per 21CFR 870.1250
Classification Name:	Catheter, Percutaneous
Product Code:	DQY

Physical Description:
The Occlusion Balloon Catheter consists of a catheter shaft with two independent lumens upon which an expandable balloon material is bonded. The "Guide Wire" lumen extends the length of the catheter and is used for placement of guide wires and injection of contrast for angiographic visualization. The "Balloon" lumen is used to inflate and deflate the balloon. Radiopaque markers at the location of the balloon provide fluoroscopic visualization of balloon placement. The outer diameter of the catheter shaft is coated with a hydrophilic polymer that reduces friction during manipulation in the vessel.

Intended Use:
The SentreHeart Occlusion Balloon Catheter is intended for temporary occlusion of large vessels in applications such as arteriography, preoperative occlusion, and emergency controlled hemorrhage procedures.

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Predicate Devices:

CODA Balloon Catheter, Cook Corp (K032869)
Equalizer Balloon Catheter, Boston Scientific (K021721)
Sentry Balloon Catheter, Boston Scientific (993292)

Safety and Performance:

Performance

Functional testing was conducted to support the claim of substantial equivalence and to demonstrate the Occlusion Balloon Catheter is safe and effective for its intended use.

Biocompatibility

The materials used in the Occlusion Balloon Catheter are commonly used materials in other medical devices. Results of testing demonstrate the Occlusion Balloon Catheter is biocompatible.

Summary:

Based on the intended use, product testing, and information provided in this notification, the subject device has been shown to be safe and effective for its intended use and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

SentreHeart Inc.
c/o Ms. Linda Guthrie
Manager, Regulatory Affairs
2468 Embarcadero Way
Palo Alto, CA 94303

Re: K070126
Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 1, 2008
Received: February 4, 2008

Dear Ms. Guthrie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K070126

Device Name: Occlusion Balloon Catheter

Indications for Use: The SentreHeart Occlusion Balloon Catheter is intended for temporary occlusion of large vessels in applications such as arteriography, preoperative occlusion, and emergency controlled hemorrhage procedures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Mayer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070126